7.7.2 LDL-cholesterol, HDL- cholesterol, total bilirubin, triglycerides

A 5 mL blood sample for LDL-cholesterol, HDL-cholesterol, total bilirubin, and triglycerides will be drawn in 5 mL red top vacutainer tubes in the morning for each primary data collection dates on Days –15, –8, –1, and 14 and at 1, 2, 3, 4, 5, 6, 9, and 12 months in a fasted state (60 mL of blood total).

Additional blood sampling for triglycerides will occur with the Oral Glucose Tolerance Testing as outlined in Section 7.10.

The samples will be processed, properly labeled, and stored at –20°C until shipped (Neptune and Phoenix sites) or delivered (Lincoln site) to MDS Pharma Services Clinical Laboratory, Lincoln, Nebraska, for analysis.

7.7.3 Total Anti-Oxidant Capacity

A 5 mL blood sample for total anti-oxidant capacity will be drawn in a 5 mL red top vacutainer tube in the morning on Days –15, –8, –1, and 14 and at the 1, 2, 3, 4, 5, 6, 9, and 12 month primary data collection dates in a fasted state (60 mL of blood total).

The samples will be allowed to clot, processed, properly labeled, and stored at –70°C until shipped (Neptune and Phoenix sites) or delivered (Lincoln site) to MDS Pharma Services Analytical Services, Lincoln, Nebraska, for analysis.

7.7.4 Carboxyhemoglobin

A 10 mL blood sample for carboxyhemoglobin analysis will be drawn in K_3EDTA vacutainer tubes at 7 AM, 11 AM, 3 PM, 7 PM, and 11 PM on Days –15, –8, –1, and 14 and at 1, 2, 3, 4, 5, 6, 9, and 12 month primary data collection dates. Note: The samples on Day –8 and at 1, 2, 4, 5, and 9 months will be limited to the 7 AM morning collection only if ambulatory urine collections are being utilized by the clinic site and the subjects are not confined. (Between 360 mL to 600 mL of blood total depending upon how many primary data collection dates are confined.). Immediately following collection, gently invert the blood samples. The whole blood samples will be properly labeled and shipped at ambient temperature for analysis to:

Source: https://www.industrydocuments.ucsf.edu/docs/skvj0001